

## BIOCOMPATIBILITY OF MEDICAL DEVICES TRAINING – THREE-DAY CERTIFICATION COURSE

### Day 1: Monday April 24, 2023

9 :00-9 :30	Check-In	
9 :30-9 :45	Introduction to NAMSA's Certification Program	Céline Puleo
9:45-10:45	Historical Review of Biocompatibility	Sylvie Framery
10h45-11:00	Break	
11:00-12:00	ISO 10993-1: Evaluation and Testing Within a Risk Management Process	Sylvie Framery
12:00-13:00	Lunch	
13:00-14:30	ISO 10993-1 (cont.)	Sylvie Framery
14:30-14:45	Break	
14:45-15:45	ISO 10993-12: Sample Preparation & Reference Materials	Alfred Dibao-Dina
15:45-17:00	ISO 10993-18: Chemical Characterization of Materials	Alfred Dibao-Dina

### Day 2: Tuesday April 25, 2023

9:30-11:00	ISO 10993-18 (cont.)	Alfred Dibao-Dina
11:00-11:15	Break	
11:15-12:30	ISO 10993-17 Establishment of Allowable Limits for Leachable Substances	Alfred Dibao-Dina
12:30-13:30	Lunch	
13:30-14:40	ISO 10993-17 (cont.)	Alfred Dibao-Dina
14:40-15:00	Break	
15:00-17:00	Biological Tests: What Manufacturers Should Know	Sylvie Framery
17:00-18:30	Evening Reception	

### Day 3: Wednesday April 26, 2023

9:30-10:45	Biological Tests: What Manufacturers Should Know (cont.)	Sylvie Framery
10:45-11:00	Break	
11:00-12:30	Regulatory Agencies' Specific Approach to Biocompatibility	Sylvie Framery
12:30-13:30	Lunch	
13:30-15:00	Developing a Biological Safety Assessment	Alfred Dibao-Dina
15:00-17:00	Break and Final Exercises	